

**Notice of Allowability**

Application No.

09/966,441

Examiner

Brian S. Kwon

Applicant(s)

SZYMCAK ET AL.

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment filed 04/24/06 & Tele. Interview on 4/28/06.
2. ☒ The allowed claim(s) is/are 29,30,32 and 35-38.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 03/21/03
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 04262006.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

  
**Brian Kwon**

**Patent Examiner**

AU 1614

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. Acknowledgement is made of applicant's submitting of the information disclosure statement (IDS) on March 21, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement (IDS) has been considered by the examiner.

2. With respect to "European Search Report for EP 02 25 6741 dated December 17, 2002" in the submitted PTO-1449, the information disclosure statement filed March 21, 2003 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office.

### **EXAMINER'S AMENDMENT**

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Timothy E. Tracy on April 28, 2006.

The application has been amended as follows:

Claim 30 (Amended) A solid dosage unit of claim 29, further comprising at least one active agent selected from the group consisting of a bisacodyl, a famotidine, a prucalopride, a diphenoxylate, a loperamide, a lactase, a mesalamine and a bismuth.

Art Unit: 1614

Claim 32 (Amended) A solid dosage unit of claim 30, wherein the active agent is loperamide.

Claim 35 (Amended) A solid dosage unit of claim 29 having from about 19 wt% to about 27 wt% silicified microcrystalline cellulose and from about 31 wt% to about 39 wt% magnesium aluminometasilicate.

Claim 37 (Amended) A solid dosage unit of claim 29, wherein the compressed admixture is a tablet having a hardness value of from about 2 to about 15 kp/cm<sup>2</sup>.

Claim 38 (Amended) A solid dosage unit of claim 37, wherein the compressed admixture is a tablet having a hardness value of from about 5 to about 10 kp/cm<sup>2</sup>.

Claims 31, 33 and 34 are cancelled.

#### ***Conclusion***

4. Claims 29, 30, 32 and 35-38 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Application/Control Number: 09/966,441  
Art Unit: 1614

Page 4

Brian Kwon  
Patent Examiner  
AU 1614

A handwritten signature in black ink, appearing to read "Brian", followed by a long horizontal line extending to the right.